

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date  
31 March 2005 (31.03.2005)

PCT

(10) International Publication Number  
**WO 2005/027821 A2**

(51) International Patent Classification<sup>7</sup>:

**A61K**

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(21) International Application Number:

PCT/IL2004/000881

(22) International Filing Date:

22 September 2004 (22.09.2004)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

158053 22 September 2003 (22.09.2003) IL  
60/503,902 22 September 2003 (22.09.2003) US

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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**WO 2005/027821 A2**

(54) Title: LARGE SCALE PREPARATION OF ALPHA-1 PROTEINASE INHIBITOR AND USE THEREOF

(57) Abstract: The present invention provides a process suitable for processing scaled-up amounts of source material in the range of tens of kilograms for the purification of alpha-1 proteinase inhibitor (API) from a mixture of unpurified proteins. More particularly, the present invention relates to a process for the purification of API from blood plasma or from plasma fractions to obtain pharmaceutical grade API on a commercial scale. The API produced by the process of the present invention is highly pure (at least 90% API out of the total protein) and highly active (at least 90% active API). The present invention also relates to pharmaceutical compositions comprising the purified API and methods of using same.